GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1474
ANSWERED ON:04.03.2016
Drug Testing
Diwakar Shri Rajesh Kumar

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is considering to ease norms for testing new drugs in the country and if so, the details thereof; and

(b) whether the norms for launch of drugs already tested in other countries are also proposed to be ceased in the country and if so, the details thereof?

Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a) & (b): The process of approval of new drugs and conduct of clinical trials has been rationalized by the Government with a view to ensure a careful assessment of the risk versus benefit to the patients, innovation vis-Ã -vis existing therapeutic options and unmet medical needs in the country. These criteria have been made an integral part of the approval process. Besides, phase I of the module for online submission of Clinical Trial applications has been operationalized. Further, the pool of Subject Experts has been increased manifold and timelines fixed for all activities. At the same time, adequate measures have been put in place to ensure the safety and welfare of patients/clinical trial subjects. It has also been decided that due consideration will be given to the fact that the drug has been approved and is in use in other countries.
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